

ARTICLE 61-07

HOSPITAL PHARMACY

Chapter
61-07-01 Hospital Pharmacy

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61-07-01-01. Definitions. For purposes of this chapter, the following definitions apply:

1. The terms "hospital" and "medical center" are synonymous.
2. "Hospital pharmacy" is defined as those portions of a hospital where drugs, medications, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as "drugs") are manufactured, produced, sold, or distributed.

History: Effective April 1, 1988.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-02. Applicability. This chapter is applicable to all hospital pharmacies as defined by section 61-07-01-01.

History: Effective April 1, 1988.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-03. Registration. All hospital pharmacies shall register annually with the board of pharmacy; certificates of registration may be issued only to those

hospital pharmacies which satisfy the provisions of all rules of the board and laws of North Dakota.

History: Effective April 1, 1988.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-04. Personnel.

1. **Director.** Each hospital pharmacy must be directed by a pharmacist-in-charge, hereinafter referred to as the director of pharmacy, who is licensed to engage in the practice of pharmacy in this state, and who is knowledgeable in and thoroughly familiar with the specialized functions of hospital pharmacies. The director of pharmacy is responsible for all activities of the hospital pharmacy, and for meeting the requirements of the North Dakota pharmacy practice act and this chapter. Contractual providers of pharmacy services shall meet the same requirements as director of pharmacy services.
2. **Supportive personnel.** The director of a hospital pharmacy must be assisted by a sufficient number of additional pharmacists and ancillary personnel as may be required to operate such pharmacy competently, safely, and adequately to meet the needs of the patients of the hospital.
 - a. Pharmacy technicians may be employed provided they have been approved by the director. The director shall develop and implement written policies and procedures to specify the duties to be performed by such technical personnel. These policies and procedures shall, at a minimum, specify that ancillary technical personnel are properly or adequately supervised by a registered pharmacist and that ancillary technical personnel are not assigned duties which may be performed only by pharmacists.
 - b. Secretarial support should be provided as required to assist with recordkeeping, report submission, and other administrative duties.
3. **Supervision.** All of the activities and operations of each hospital pharmacy must be personally and directly supervised by its director or pharmacist's designee. All functions and activities of ancillary personnel must be personally and directly supervised by a sufficient number of registered pharmacists to ensure that all such functions and activities are performed competently, safely, and without risk of harm to patients.

History: Effective April 1, 1988.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-05. Absence of pharmacist.

1. **General.** During such times as a hospital pharmacy may be unattended by a pharmacist, arrangements must be made in advance by the director for the provision of drugs to the medical staff and other authorized personnel of the hospital, by use of night cabinets or floor stock, or both, and in emergency circumstances, by access to the pharmacy. A pharmacist must be available for consultation during all absences; this protocol can be accomplished by telephone.
2. **Night cabinets.** If night cabinets are used, the following should prevail: absence of a pharmacist, must be by locked cabinets or other enclosures constructed and located outside of the pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons by force or otherwise. The director shall, in conjunction with the appropriate committee of the hospital, develop inventory listings of those drugs to be included in such cabinets and shall ensure that:
 - a. Such drugs are available therein, properly labeled.
 - b. Only prepackaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements.
 - c. Whenever access to such cabinets shall have been gained, written physician's orders and proofs of use, if applicable, are provided.
 - d. Written policies and procedures are established to implement the requirements of this subsection.
3. **Access to pharmacy.** Whenever any drug is not available from floor supplies or night cabinets, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy in accordance with the requirements of this section. One supervisory registered professional nurse and only one in any given eight-hour shift is responsible for removing drugs therefrom. The responsible nurse, in times of emergency, may delegate this duty to another nurse. The responsible nurse must be designated by position, in writing, by the appropriate committee of the hospital and, prior to being permitted to obtain access to the pharmacy, shall receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required. Such education and training must be given by the director of pharmacy, who shall require, at a minimum, the following records and procedures:
 - a. Removal of any drug from the pharmacy by an authorized nurse must be recorded on a suitable form showing patient name, room number, name of drug, strength, amount, date, time, and signature of nurse.

- b. Such form must be left with the container from which the drug was removed, both placed conspicuously so that it will be found by a pharmacist and checked properly and promptly; or, in the case of a unit dose, place an additional dose of the drug, or the box, on the form.
- 4. **Emergency kits.** Emergency drugs, as approved by the medical staff, must be in adequate and proper supply in the pharmacy and in designated hospital areas. The pharmacist is responsible both for the contents of emergency medication carts, kits, and for the inspection procedure to be used.

History: Effective April 1, 1988.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-06. Physical requirements.

- 1. **Area.** A hospital pharmacy shall have within the hospital its services, sufficient floor space allocated to it to ensure that drugs are prepared in sanitary, well-lighted, and enclosed places, and which meet the other requirements of this section.
- 2. **Equipment and materials.** Each hospital pharmacy shall have sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations, and, as a minimum, access to the references for the following subjects:
 - a. Drug interactions.
 - b. Drug compatibility.
 - c. Poison and antidote information.
 - d. Chemistry:
 - (1) Organic;
 - (2) Pharmaceutical; and
 - (3) Biological.
 - e. Toxicology.
 - f. Pharmacology.
 - g. Bacteriology.
 - h. Sterilization and disinfection.

- i. Pharmacy technology.
- j. Patient counseling.
- k. Rational therapy.
- l. Pathology.
- m. Current United States Pharmacopeia and National Formulary dispensing information.
- n. Current state and federal regulations applicable to controlled substances.

The technical equipment required by section 61-02-01-03 may be either at the hospital pharmacy or the community pharmacy servicing the hospital pharmacy.

- 3. **Storage.** All drugs must be stored in designated areas within the hospital pharmacy which are sufficient to ensure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security.
- 4. **Alcohol and flammables.** Alcohol and flammables must be stored in areas that shall meet, at a minimum, basic local building code requirements for the storage of volatiles and such other laws, ordinances, or regulations as may apply.
- 5. **Unattended areas.** In the absence of authorized personnel, and whenever any area of a hospital pharmacy is not under the personal and direct supervision of authorized personnel, such area must be locked.
- 6. **Security.** All areas occupied by a hospital pharmacy must be capable of being locked by key or combination, so as to prevent access by unauthorized personnel. The director shall designate, in writing, by title and specific area, those persons who shall have access to particular areas within the pharmacy.

History: Effective April 1, 1988.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 43-15-10(9), 43-15-10(11), 43-15-10(12), 43-15-10(14)

61-07-01-07. Drug distribution and control.

- 1. **General.** The director of pharmacy services shall establish written procedures for the safe and efficient distribution of pharmaceutical products. An annual updated copy of such procedures must be on hand for inspections.

2. **Responsibility.** The director is responsible for the safe and efficient distribution of, control of, and accountability for drugs. The other professional staff of the hospital shall cooperate with the director in meeting this responsibility and in ordering, administering, and accounting for pharmaceutical materials so as to achieve this purpose. Accordingly, the director is responsible for, at a minimum, the following:
- a. Preparation and sterilization of parenteral medications manufactured within the hospital.
 - b. Admixture of parenteral products, including education and training of nursing personnel concerning incompatibility and provision of proper incompatibility information when the admixture of parenteral products is not accomplished within the hospital pharmacy.
 - c. Manufacture of drugs, if applicable.
 - d. Establishment of specifications for procurement of all materials, including drugs, chemicals, and biologicals, subject to approval of the appropriate committee of the hospital.
 - e. Participation in development of a formulary for the hospital.
 - f. Filling and labeling all containers from which drugs are to be administered.
 - g. Maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and inpatient care areas, as well as current antidote information, telephone numbers of regional poison control centers, and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the hospital, if any.
 - h. Records of all transactions of the hospital pharmacy as may be required by applicable law, state and federal, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials.
 - i. Participation in drug usage evaluation activities.
 - j. Full cooperation with teaching or research programs, or both, in the hospital, if any.
 - k. Implementation of the policies and decisions of the appropriate committees of the hospital.

- l. Effective and efficient messenger and delivery service to connect the pharmacy with appropriate parts of the hospital on a regular basis throughout the normal workday of the hospital.
- m. Meeting all compliance and other requirements of the North Dakota board of pharmacy rules and laws and this chapter.

3. Labeling.

- a. For use inside the hospital. All drugs dispensed by a hospital pharmacy, not on an individual prescription, intended for use within the hospital, must be dispensed in appropriate containers and adequately labeled so as to identify, at a minimum, brand name or generic name, strength, quantity, source, and expiration date.
- b. For use outside the pharmacy. All drugs dispensed by a hospital pharmacy to patients about to be discharged or to whom it is certain will carry the item dispensed outside of the hospital, in compliance with pharmacy practice act and rules, must be labeled with the following information:
 - (1) Name, address, and telephone number of the hospital pharmacy.
 - (2) Date and identifying serial number.
 - (3) Full name of patient.
 - (4) Name of drug strength, and number of units.
 - (5) Directions for use to the patients.
 - (6) Name of physician prescribing.
 - (7) Required precautionary information regarding controlled substances.
 - (8) Such other and further accessory cautionary information as may be required or desirable for proper use and safety to the patient.
- c. Drugs added to parenteral admixtures. Whenever any drugs are added to parenteral admixtures, whether within or outside the direct and personal supervision of a pharmacist, such admixtures must be labeled with a distinctive supplementary label indicating the name and the amount of the drug added, date and time of addition and expiration, and name of person so adding.

4. **Discontinued drugs.** The director shall develop and implement policies and procedures to ensure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition or that the director or the director's designee make proper disposition or dispose of such drugs at the storage site.
5. **Physician's orders.** Drugs may be dispensed from the hospital pharmacy only upon written or verbal orders, direct copies or facsimiles thereof, of authorized physicians. Verbal orders for drugs are accepted only by personnel so designated in accordance with applicable law and regulations governing such acts and in accordance with the approved medical staff rules and regulations.
 - a. Authorization. The appropriate committee of the hospital shall designate, from time to time as appropriate, those physicians who are authorized to issue orders to the pharmacy.
 - b. Abbreviations. Orders employing abbreviations and chemical symbols may be utilized and filled only if such abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the hospital.
 - c. Requirements - Orders for drugs for use by inpatients. Orders for drugs for use by inpatients shall contain, at a minimum: patient name and room number, drug name, strength, directions for use, date, and physician's signature or that of the physician's authorized representative.
 - d. Requirements - Orders for drugs for use by outpatients. Orders for drugs for use by outpatients become prescriptions and must meet all requirements of the law.
 - e. Pharmacist review. The pharmacist shall review the prescriber's order, or a direct copy thereof, before the initial dose of medication is dispensed (with the exception of emergency orders when time does not permit). In cases when the medication order is written when the pharmacy is "closed" or the pharmacist is otherwise unavailable, the medication order should be reviewed by the pharmacist as soon thereafter as possible, preferably within twenty-four hours.
 - f. Signature. A means of identifying the signatures of all practitioners authorized to use the pharmaceutical services, as well as a listing of their drug enforcement administration numbers, must be maintained.
6. **Controlled drug accountability.** The hospital shall establish effective procedures and maintain adequate records regarding use and

accountability of controlled substances and such other drugs as the appropriate hospital committee may designate which may specify at least the following:

- a. Name of drug.
 - b. Dose.
 - c. Physician.
 - d. Patient.
 - e. Date and time of administration.
 - f. Person administering the drug.
7. **Recall.** The director shall develop and implement a recall procedure that can be readily activated to assure the medical staff of the hospital that all drugs included on the recall, whether within or outside the hospital, are returned to the pharmacy for proper disposition.
 8. **Suspected adverse drug reactions.** Any and all suspected adverse drug reactions must be reported orally immediately to the ordering physician and in writing to the pharmacy, and to the appropriate committee of the hospital. Appropriate entry on the patient's record must also be made. The director may, at the director's discretion, make further reports of such suspected reactions to the hospital reporting program of the United States food and drug administration, to the manufacturer, and to the United States pharmacopeia.
 9. **Records and reports.** The director shall maintain and submit, as appropriate, such records and reports as are required to ensure patient health, safety, and welfare, and, at a minimum, the following:
 - a. Physician's orders, direct copies, or facsimiles thereof.
 - b. Controlled drug accountability report.
 - c. Reports of suspected adverse drug reactions.
 - d. Inventories of night cabinets and emergency kits.
 - e. Inventories of the pharmacy.
 - f. Biennial controlled substances inventories.
 - g. Alcohol and flammables reports.

- h. Such other and further records and reports as may be required by law and this chapter.

10. Distribution systems.

- a. Floor or ward stock system. In this system, all but the most unusual drug items are stocked on the nursing stations. Drug products which require special control (e.g., antineoplastic agents) are often omitted from floor stock, and are sent to the nursing unit upon receipt of a prescription order for the individual patient. All containers used for floor stock must meet specific labeling requirements as addressed in these rules.
- b. Individual prescription order system. In this system, all medications are dispensed by the pharmacist on individual prescription orders.
- c. Combination of floor stock and the individual prescription order system. In this system, most drugs are dispensed on an individual prescription basis. The remaining drugs are obtained via limited floor stock.
- d. Unit dose. In this system, medications are contained in single unit packages; they are dispensed in as ready-to-administer form as possible, for most medications. All doses will be labeled properly to include name, strength, expiration date, or lot number or control number, or both.

History: Effective April 1, 1988.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-08. Nondistributive roles of the pharmacist. These functions include, but are not limited to, chart review; audits; clinical tasks; committee participation; drug information; inservice training of the pharmacists, the pharmacy staff, and other health professionals; poison control; nursing unit inspections; preparation of medication histories; monitoring of drug therapy; patient education; detection and reporting of adverse drug reactions; drug therapy selection; participation in drug usage evaluation; and other quality assurance programs.

History: Effective April 1, 1988.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-09. Administration of drugs.

- 1. **General.** Drugs may be administered at a hospital only upon the orders of those members of the medical staff who have been granted clinical privileges or who are authorized members of the house staff and, by authorized licensed hospital personnel in accordance with policies and

procedures specified by the appropriate committee of the facility, under applicable law and rules, and by usual and customary standards of good medical practice.

2. **Self-administration.** Self-administration of drugs by patients may be permitted only when specifically authorized by the treating or ordering physician; provided, however, the patient has been educated and trained in the proper manner of self-administration and there is no risk of harm to the patient or others. The label should contain patient's name, room number, date directions, and name and strength of medication, at a minimum.

History: Effective April 1, 1988.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-10. Drugs from outside sources.

1. **Outside pharmacies.** Whenever drugs or pharmaceutical services are obtained from outside of a hospital, arrangements must be made to ensure that such outside pharmacist provides services with sufficient professionalism, quality, and availability to adequately protect the safety of the patients and to properly serve the needs of the hospital. Such arrangements must be made in writing and must, at a minimum, specify that:
 - a. The outside pharmacist shall act in the capacity of the director (subsection 1 of section 61-07-01-04) and, therefore, is subject to this chapter.
 - b. Such arrangement is contingent upon approval of the board of pharmacy.
 - c. The pharmacist must be available for consultation during all absences, or provide a protocol to contact another pharmacist.
 - d. Adequate storage facilities for drugs will be provided.
 - e. All drugs supplied must be labeled so as to ensure that recalls can be effected and that proper control and supervision of such drugs may be exercised.
2. **Brought by patients.** Whenever patients bring drugs into a hospital, such drugs may not be administered unless they can be precisely identified; administration must be pursuant to a physician's order only.

The director of pharmacy will specify the policy and procedure for handling these medications.

History: Effective April 1, 1988.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-11. Quality assurance. The director of pharmacy services is responsible for developing procedures for an ongoing quality assurance program of pharmaceutical services that includes a mechanism for reviewing and evaluating drug-related patient care, as well as an appropriate response to findings. This written plan should clearly establish responsibility and the need for documentation of an effective program.

The director of pharmacy services is responsible for developing procedures for quality assurance in centralized intravenous admixture services. Such procedures must encompass selection, education, and training of personnel, inprocess controls, end-product testing, and sampling guidelines. Cautionary measures for the safe admixture of parenteral products must be developed.

History: Effective April 1, 1988.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-12. Investigational drugs. Investigational drugs must be properly labeled and may be administered only under the personal and direct supervision of the principal physician-investigator or physician-investigator's authorized clinician with prior approval of the appropriate committees of the hospital. Nurses may administer such drugs only after they have been educated and trained concerning relevant pharmacologic information about such drugs by the clinician or the pharmacist. A central unit must be maintained wherein essential information regarding such drugs may be obtained. Patients' or representatives' informed consent must be obtained prior to investigational drug therapy. Investigational drugs must be stored under the same regulations as Schedule II controlled substances.

History: Effective April 1, 1988.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-07-01-13. Inspection.

1. **Monthly.** The director of pharmacy shall inspect, no less than once a month, personally or by qualified designee, all matters within the director's jurisdiction and responsibility and make appropriate written records and notations of such inspections. Such inspections shall verify, at a minimum, that:
 - a. Drugs are dispensed only by pharmacists.

- b. Ancillary pharmacy personnel are properly directed and supervised.
 - c. Disinfectants and drugs for external use are stored separately and apart from drugs for internal use or injection.
 - d. Drugs requiring special storage conditions to ensure their stability are properly stored.
 - e. Outdated drugs or otherwise unusable drugs have been identified and their distribution and administration prevented. An area must be designated for authorized storage of such drugs prior to their proper disposition.
 - f. Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and medical personnel.
 - g. Emergency drugs designated pursuant to subsection 4 of section 61-07-01-05 are adequate and in proper supply both within the pharmacy and at outside storage locations.
 - h. All necessary and required security and storage standards are met.
 - i. Metric-apothecaries' weight and measure conversion tables and charts are reasonably available to all medical personnel.
 - j. All policies and procedures of the director and of appropriate committees of the hospital relevant to pharmacy are followed.
 - k. The telephone number of the regional poison control information center should be posted by all telephones in the nursing stations where drugs are stored.
2. **Annual.** The board of pharmacy shall inspect, no less than once a year, by one of its members or by its qualified designee, all aspects of the management and operation of all hospital pharmacies in the state, to verify compliance with the law, this chapter, and such other standards as may be appropriate to ensure that the health, safety, and welfare of patients of the hospital serviced by the pharmacy are protected. Written reports of an inspection must be filed with the board and the director. Any discrepancies or deficiencies noted must be corrected within a reasonable time. Written notice of such corrections must be filed with the board. Board recommendations may be questioned by written notice to the executive secretary of the board of pharmacy. Consideration must be given by the board's inspector or designee to giving thirty days' notice of an inspection to the director of the pharmacy to be visited. Consideration must also be given to any

recent survey by the joint commission on accreditation of health care organizations.

History: Effective April 1, 1988.

General Authority: NDCC 28-32-02

Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)